4D LV-Function© 2.2

Operating Manual

Edisonstr. 6 – 85716 Unterschleissheim – Germany
Phone +49 (0)89-32175-500 | Fax +49 (0)89-32175-750
Foremail: info@tomtec.de

0 Table of Contents

1 Introduction

In the following text **TomTec Imaging Systems GmbH** will be called **TomTec**.

1.1 About this manual

Page and chapter numbers are displayed at the bottom of each page. The chapter number is displayed first, followed by a dash, then the page number.

Examples, suggestions and warnings are included to help you to get started and to give you advise on important setups and results. This information is indicated via symbols. The explanations for those symbols are:

The caution symbol indicates the most important information, safety precautions, or warnings.

The stop symbol highlights important information. You should stop and read before continuing.

The bulb symbol indicates a suggestion or an idea that simplifies using the software. It can also refer to information available in other chapters.

1.2 Interpreting symbols on the product

Symbol	Location	Description
	Software CD, Packaging	Read operating manual prior to use.
	Software CD	Production Year and month
	Software CD, Packaging	Product complies with 93/42/EEC annex II, and annex VII Product according to rule 10, (Class IIa)
	Software CD	Lot-Number of Software: Indicates the lot code and revision level of the software.
REF	Software CD	Reference Number and Order Code of the product
Reg. No.	Software CD	TomTec Registration number

1.3 System Description

4D LV-Function is a clinical application package for high performance PC platforms based on Microsoft Windows™ operating system standards. 4D LV-Function is software for the reconstruction, rendering and analysis of digitized ultrasound images.

4D LV-Function is designed for the 2- and 3-dimensional morphological and functional analysis of left ventricles (LV). Based on three dimensional datasets a semi-automatic 3D contour finding algorithm supports the calculation of a 4D model (Beutel) that represents the cavity of the LV. From that model global as well as regional volumetric changes can be derived.

1.4 Intended Use

4D LV-Function is intended to analyze digital ultrasound images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing.

The 4D LV-Function reads certain digital 3D/4D image file formats for reprocessing to a proprietary 3D/4D image file format for subsequent 3D/4D tomographic reconstruction and rendering. It is intended as a general purpose digital 3D/4D ultrasound image processing tool for cardiology.

1.5 Safety Precautions

Please read the information in this section carefully before using the program. This section contains important information on operating safety and handling of the program as well as information on service and support.

1.5.1 Data handling

Saved analyses are only stored as long as there is free disk space available. In case of there not being enough disk space available, older studies are removed.

Saved analyses are not automatically backed up nor backed up with the host platform data. Please contact your service representative for backup.

1.5.2 Installation and maintenance

Only TomTec trained and authorized personnel may perform installation, setup, upgrade, maintenance, service and any modification of TomTec products; otherwise, warranty may be void.

Technical documentation is only available together with an adequate training. Please contact TomTec for further information.

TomTec Imaging Systems GmbH assumes no liability for problems attributable to unauthorized modifications, additions or deletions to TomTec Imaging Systems GmbH software or hardware, or unauthorized installation of third party software.

As manufacturer and distributor of this product, TomTec is not responsible for safety, reliability and performance of the system, if:

- installation, configuration or modifications are performed by persons, who are not authorized by TomTec.
- the product is not operated in accordance with the operating manual.
- the product is operated outside of its operating conditions.

The customer is responsible for all changes to the system settings. This can lead to system damage and warranty void.

The customer is responsible for the installation of any third party software. The software may be incompatible to TomTec software. Contact your local TomTec representative for further information on installing third party software.

1.5.3 Patient / user safety

The user must be satisfied with the suitability and completeness of a study for an analysis with 4D LV-Function. If not, the acquisition has to be repeated. For information about performing an acquisition, which is suitable for an analysis with 4D LV-Function, please refer to the operating instructions provided by the manufacturer of your ultrasound equipment.

The information contained in this manual is intended only for the operation of TomTec systems and software. It does not include information on echocardiograms or general ultrasound acquisition. Please refer to the operating instructions of your ultrasound equipment for further information.

U. S. Federal law restricts this device (or software package) to be sold by or on the order of a licensed medical practitioner.

1.5.4 Measurements

The customer is responsible for determining if artifactual characteristics exist. Artifacts can severely affect the image quality and require a reacquisition. Examples of artifacts are:

- Obvious discontinuity due to a jerky motion during acquisition or because the acquisition range was left
- Excess shadowing of images
- Poorly defined anatomy or evidence of distorted anatomical representation

In the case of a poorly reconstructed image, as determined by the above criteria or by the operator's clinical experience and training, dimensional measurements should not be made. If for any reason measurements are made using a poorly reconstructed image, these measurements should not be used for making diagnostic decisions.

The operator must be committed to the accuracy of the existing images and measurement results. Image scans should be repeated if there is the slightest doubt as to the accuracy of images and measurements.

The ECG trace displayed in this product is intended only for basic rhythm identification, and not for diagnostic purposes.

The customer is responsible for determining if the desired measurement is suitable for the corresponding dataset and for determining if the measurement results are applicable for diagnostic decisions. In case of M Mode, Doppler and 2D Images measurements only the desired and reasonable measurement packages should be used for the according images. In case of incorrect usage incorrect results may occur.

Measurement accuracy

The measurement accuracy of any measurement function is only as precise as the maximum acquired resolution in the screen projection of an image. The accuracy depends mainly on the acquisition method and the operator skills. For detailed information about acquisition methods and accuracies refer to the manual of the acquiring device.

All measurements are calculated from the relative positions of on-screen graphic symbols superimposed over the ultrasound image. Therefore, the validity of the measurements with respect to the ultrasound image depends directly on the operator skills in positioning the graphic symbols over features of interest in the image. When performing measurements, always be aware of this source of human error.

Mandatory requirements for each measurement are the correct reproduction of the acquired anatomy and the performing of measurements according to the 'lege artis' standard.

The accuracy of the Measurement Tools was verified on a representative test-phantom. The following table represents the measurement range and the accuracy of measurement functions:

	Volume 4D-LV
additional comments	The left ventricle has to be complete in the Contouring Window and must be more than 70% of the acquired sector.
Tolerance	± 5 %

The system is not developed to have an automatic diagnostic tool. The 4D LV-Function software provides suggestions for the contour finding. Starting with these suggestions the user has to adjust the settings for the contour and has to accept the calculated contour suggestion.

The contour finding and the calculation of the 4D-Volume should be repeated if there is the slightest doubt as to the accuracy of the contour suggestions or 4D-Volume.

The customer is responsible for the definition of LV contours in acquired views.

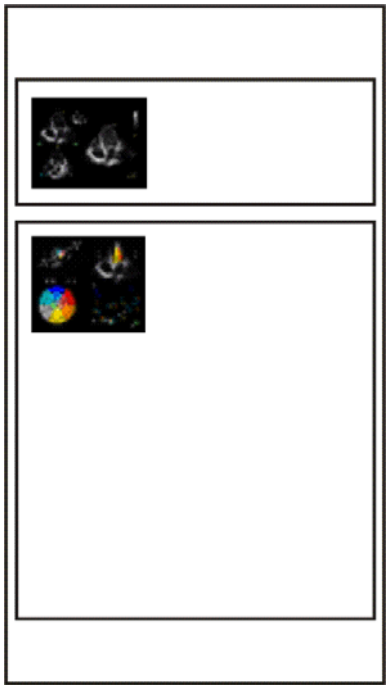
2 Installation

This chapter guides you through the installation and licensing process. Use the CD-ROM you have received with your TomTec software for installation.

Log in as **"Administrator"** before starting the installation. This TomTec software requires **Microsoft® Windows XP Professional™** or **XP Embedded**.

3 Functional Reference

4D LV-Function is started from Host System. 4D LV-Function immediately starts with the Selected Image, if there are no Bookmarks created before. If there are any previously created Bookmarks, the application stops at the following display and requires a decision.



Example: The upper box displays the Selected Image and the lower one displays available Bookmarks

3.1 Differences between Vivid 7 Systems and EchoPAC PC

The usage of 4D LV-Function on Vivid 7 ultrasound systems differs slightly from EchoPAC PCs.

One point is the nomenclature of the mouse buttons and mouse wheel which varies as follows:

- The **left mouse button** is represented by the **Select** key on the Vivid 7 panel.
- The **right mouse button** is represented by the **Update / Menu** key on the Vivid 7 panel.
- The **mouse movement** is represented by the **trackball**.
- The mouse wheel has no counterpart on the Vivid 7 panel.

The general workflow on Vivid 7 systems is the same as on EchoPAC PCs, whereas the trackball-button interaction is different from the normal mouse handling.

All actions on the EchoPAC PC that demand to hold a mouse button pressed while moving the mouse are replaced by a lock mechanism on Vivid 7 systems. That means that instead of keeping the button pressed the user has to lock the cursor with one click on the Select button, moves the trackball and relieves the cursor again with one click after completing the action.

An exception is the rotation navigation feature for view adjustments during the Set Initial Contours State (Refer to chapter **3.7 View Adjustment**). The Virtual Mouse Wheel replaces the trackball in order to rotate the views about the long axis in this case. On EchoPAC PC that rotation can be done via the mouse wheel too.

3.2 Bookmark Window

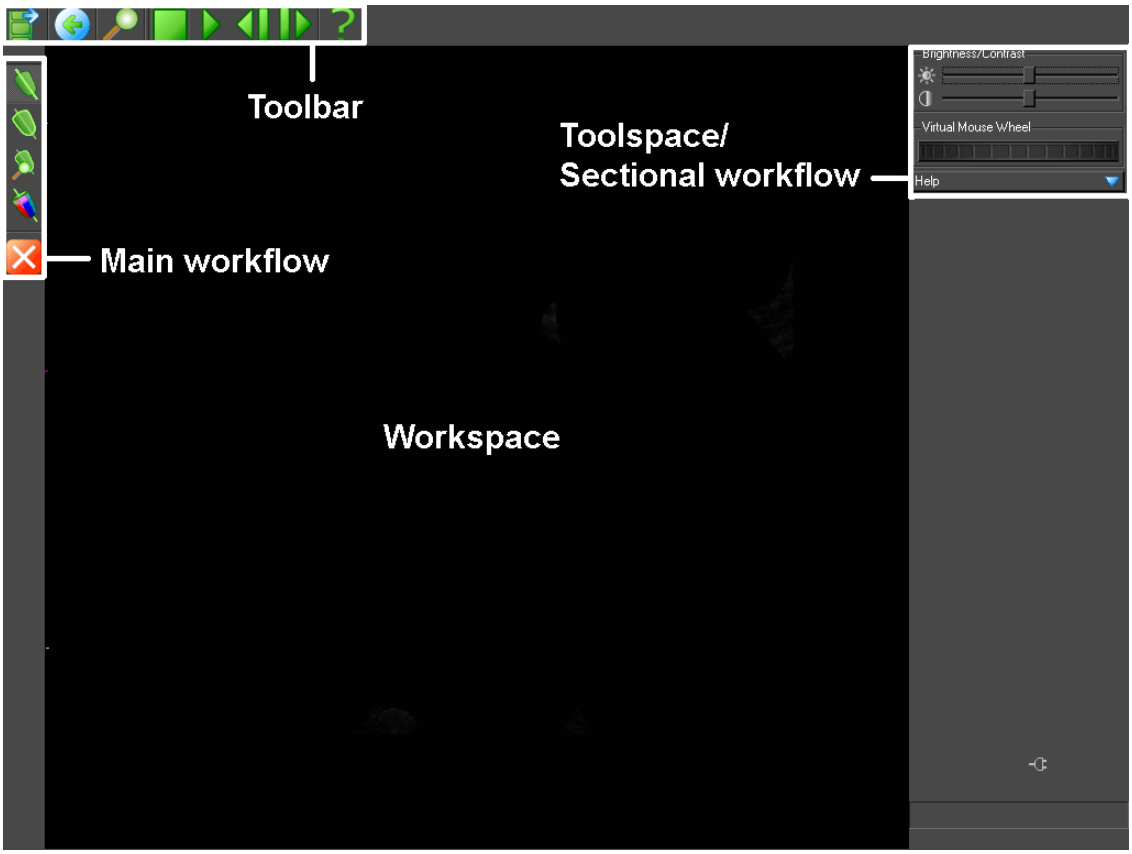
The Bookmark Window contains images shown as thumbnails. These items are called Bookmarks. They are previously analyzed clips which can be restored for analysis.

Item context menu(right mouse click)	Function
4D LV-Function	starts the selected item with the 4D LV-Function.
Double click the item	starts the selected item with the 4D LV-Function.
Delete Bookmark	deletes the marked item.
Edit Label	opens a dialog for editing the label of this Bookmark.

3.3

3.4 Interface Elements of 4D LV-Function

This section presents a general overview of the main interface elements.



Interface Elements of 4D LV-Function

Interface element	Description
Main workflow	A top down workflow, which guides the user through review and measurement of his examination.
Toolbar	provides easy access to the most often used functions on the respective screen.
Toolspace / Sectional workflow	offers special functions for analysis and measurement.
Workspace	displays the contents of the clinical data and analysis in a diagnostic area.

3.5 Workflow

The desktop of 4D LV-Function consists of four main screens:

View Adjustment

The **Adjust long axis** Display allows standard apical views of the left ventricle.

Initial Contours

The **Set initial contours** Display allows the easy and intuitive definition of end-systolic and end-diastolic initial contours by the user.

Contour Revision

The **Contour Revision** Display shows the evaluated and optimized dynamic Beutel(Evaluated and optimized dynamic model of the left ventricle) generated based on the information of the previous workflow steps. The aim of Beutel Revision is to provide quick and easy ways to review the results of the contour detection. Editing features allow the user to manually support / edit the quality of the contour detection.

4D LV Analysis

The **4D LV Analysis** Display offers two MPRs(Multi planar reconstruction of an image) with different overlays, the volume object divided in 16 segments(ASE) for regional and global analysis.

All functions can easily be accessed by the buttons of the Toolbar and/or Toolspace.

3.6 General Review Tools

Toolbar

Button	Name	Function
	**Export**	exports a screen shot (still frame or movie). This screenshot will be exported to a user selectable target directory.
	**Reset**	displays the dataset as originally displayed in the beginning.
	**Zoom**	Keep the left mouse button pressed and move the mouse to zoom the image in and out.

Playbar Tools at the Toolbar

	**Stop Phase Loop**	stops the animation of a displayed phase sequence.
	**Play Phase Loop**	starts the animation of a displayed phase sequence.
	**Previous Phase**	shows the previous phase.
	**Next Phase**	shows the succeeding phase.

	About	opens a box with product maintenance information and access to manual.

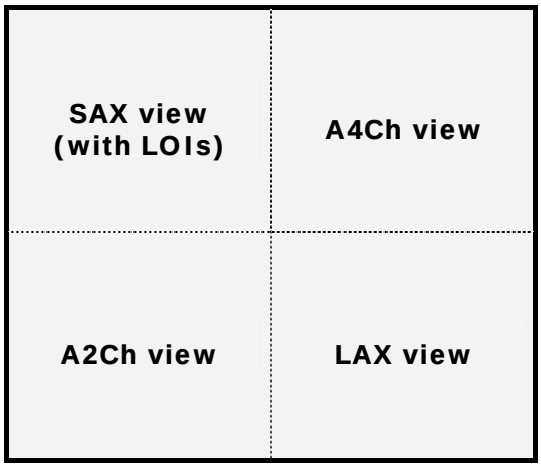
Workspace

Button / Item	Name	Function
	Single Tiling	uses the whole diagnostic image area to display the active view in full size.
	Quad Tiling	displays 4 windows within diagnostic image area.

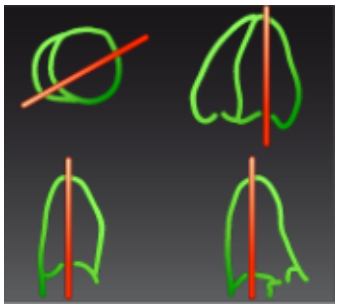
3.7 View Adjustment

After the **4D LV-Function** application has been started, the **Adjust long axis** Display will be opened. It can also be entered via the **Adjust long axis** button.

The **Adjust long axis** Display allows the definition of the long axis definition for standard apical views. It offers an adjustment if the long axis could not be aligned with the transducer's main axis. It is recommended to acquire the 3D data already in such a way that the LAX is aligned with the transducer axis to minimize the work.



Tiles at the step: LV-Analysis View Adjustment



Mouse functions for MPR manipulations

Button	Function
Left Mouse Button (Pivot mode) 	Keep the left mouse button pressed and move the mouse to rotate the selected LAX image around a virtual transducer point. All four MPRs change accordingly. Keep the left mouse button pressed on to the double arrow on top of the white SAX LOI(The Line Of Intersection represents the cross section of another imaging plane with the currently displayed one) and move the mouse to reposition the SAX MPR vertically or to slice(Functionality for moving in parallel slices through a dataset) through the data set. Pivot(Functionality for the rotation of a reconstruction around its vertical/horizontal axis)
Right Mouse Button (Pan mode) 	Keep the right mouse button pressed and move the mouse to relocate the selected LAX image within its tile. Pan(Functionality for the relocation of an image/reconstruction within its tile)
Mouse Wheel (Rotation mode) 	**Mouse pointer within SAX or A4Ch view(Apical 4 Chamber view of the heart):** Rotate the mouse wheel to rotate the data set around the common center axis (“common Long axis”) of all MPR views (static Line Of Intersection further called LOI, data set is moving). **Mouse pointer within LAX view:** Rotate the mouse wheel causes the respective MPR (purple) to rotate around its center. This feature allows changing the initial, rigid 60 degree long axis MPR relationship (static data set is moving). **Mouse pointer within A2Ch view(Apical 2 Chamber view of the heart):** Rotate the mouse wheel causes the respective MPR (blue) to rotate around its center. This feature allows changing the initial, rigid 60 degree long axis MPR relationship (static data set is moving).

Acquiring the data in such a way leaving the left ventricle parallel to the ventricle long axis and the four chamber view displayed in the main plane of the ultrasound system, reduces the analysis time within that workflow.

3.7.1 Worksteps

Use the image provided by clicking the Help button at the Toolspace for an easier understanding of the following workflow.

The following description shows the workflow for LV-Analysis View Adjustment.

1.) **Adjust long axis.** Use the **Brightness** and **Contrast** sliders to display the dataset with the specific details needed for your analysis. The A4Ch view is used as reference plane for spatial relation between segment model and physical heart. Initially A2Ch and LAX views are derived automatically by maintaining an equidistant 60 degree rotation angle between the cut planes.
Use the Mouse functions (Pivot and Pan mode) for MPR manipulations to align the data Long Axis with the left ventricle. Determine the A4Ch view. Now the data set is registered with the 16 segment model. After that check whether the result of the other two views (A2Ch and LAX) satisfy your demands. If not, adapt the view(s) to your satisfaction.

2.) **Adapting the A2Ch and LAX views.** If necessary, the views can be adapted by using the Rotation mode to change the initial, rigid 60 degree long axis MPR relationship.

3.) **Adjust the SAX LOI.** Point onto a double arrow on top of the white SAX LOI to move the SAX MPR vertically. This feature only affects the SAX view in the upper left tile. Position the SAX LOI this way, that the SAX view represents a good impression of the LV. This function can be further used for slicing along the LAX.

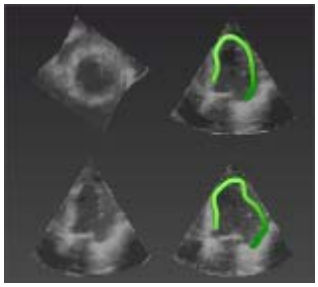
Button, icon	Name	Function
	**Brightness**	lightens or darkens tissue and colors equally.
	**Contrast**	adjusts the difference between light and dark tissue as well as light and dark colors.
	Virtual Mouse Wheel	An alternative symbol for mouse wheel rotation is displayed in the tool space to enable LOI rotation like previously described under Mouse Wheel (Rotation mode).

3.8 Initial Contours

The **Set initial contours** Display can be entered via the **Set initial contours** button. This display allows the easy and intuitive definition of end-systolic and end-diastolic initial contours drawn by the user.

Dynamic SAX view (data set with LOIs)	**Static LAX view (Endsystole)**
Dynamic LAX view	**Static LAX view (Enddiastole)**

Tiles at the step: Initial Contours



3.8.1 Worksteps

Use the image provided by clicking the Help button at the Toolspace for an easier understanding of the following workflow.

The following description shows the workflow for Beutel Initialization.

1.) **Set initial contours.** Use the **Brightness** and **Contrast** sliders to display the dataset with the specific details needed for your analysis. Use the default **View** to trace the contours at the endsystolic and enddiastolic static images or select another one. Place the first point of the contour spline with a click within one of the static images at the upper or lower right tiles. Trace the contour (green) and define the position of the last spline point with a double click. Redo this on the other static image.

2.) **Select another view.** Check the position of the shown extrapolated contours in turquoise based on the preceded initial contours. This extrapolated contour cannot be changed. If it does not meet the expectations of the user, your own contour tracing can be performed. The extrapolated contour disappears and is replaced by the newly

drawn contour. Select the next view and check the displayed contour proposal. If it does not meet the expectations, proceed like described before.

Drawing the initial contour exactly within the 4CH view and all other views reduce the needs of manual contour in the workflow Contour Revision.

3.) **Edit an existing (green) contour.** Select the view whose contours should be edited.

- Click on a segment between two neighboring points to set the new support point.
- Click with the right mouse button on a support point to remove it from the spline.
- Keep the left mouse button pressed over the support point, which has to be shifted. Move the mouse to shift this support point to another location.

Button, icon	Name	Function
	**Brightness**	lightens or darkens tissue and colors equally.
	**Contrast**	adjusts the difference between light and dark tissue as well as light and dark colors.
	**4 Chamber View**	displays A4CH View images.
	**2 Chamber View**	displays A2CH View images.
	**LAX**	displays LAX View images.
	**Delete contours in current view**	removes only the contours of the currently active view. The other contours will remain.

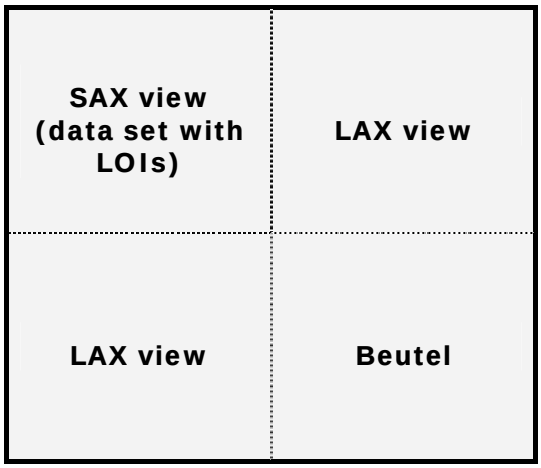
Based on the initial contours 4D LV-Function calculates an initial model for the endsystolic and enddiastolic frame. 4D LV- Function starting from that model searches for the endocardial contour within the complete 3D volume and for every frame.

3.9 Contour Revision

The **Contour Revision** Display can be entered via the **Contour Revision**  button. This display shows the evaluated and optimized dynamic model of the left ventricle generated based on the information of the workflow steps before. The aim of Contour Revision is to provide quick and easy ways to review the results of the contour detection. Editing features allow the user to manually support / edit the quality of the contour detection.

The two LAX views are rotated around the long axis of the ventricle, which has been defined in the first workflow step. The third MPR view (SAX view) is orthogonal to the long axis. In

all four windows it is possible to switch from the standard four tile screen to a single tile screen.



Tiles at the step: Contour Revision

Mouse functions for MPR manipulations

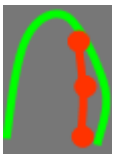
Button	Function
Left Mouse Button	Keep the left mouse button pressed and move the mouse to rotate the Beutel around a virtual point.
Mouse Wheel if available	**Mouse pointer within SAX or LAX views:** Rotate the mouse wheel to rotate the common center axis (“common Long axis”) of all MPR views (LOI is moving, static SAX data set) around the LV long axis. All MPRs are changed accordingly. Or: Keep the left mouse button pressed outside of the white circle and move the mouse to rotate the common center axis of all MPR views.
Left Mouse Button (Slice mode / SAX MPR position)	Keep the left mouse button pressed on to the double arrow on top of the white SAX LOI and move the mouse to reposition the SAX MPR vertically or to slice through the data set.

Use the image provided by clicking the Help button at the Toolspace for an easier understanding of the local contour detection.

Toolbar

Button	Name	Function
	**Undo**	undoes the last operation.

	**Redo**	redoes the last operation.

Button, slider, icon	Name	Function
	**Brightness**	lightens or darkens tissue and colors equally.
	**Contrast**	adjusts the difference between light and dark tissue as well as light and dark colors.
Contour Detection Sensitivity		
 to 	**Contour Detection Sensitivity**	Contour detection sensitivity allows the adaptation of the contour finding to the attributes and the quality of the dataset. The contour finding algorithm can calculate with three different settings. Choose the button, which produces the best contour.
Contour Guides		
	**Add Curve** 	Draw guides into the MPR views to specify desired positions of the Beutel surface, in case the surface does not represent the anatomical structure of the LV well enough. Define single points with left mouse clicks and finish the tracing with a double click. For editing a guide refer to chapter **3.8.1 Worksteps Edit an existing (green) contour.**
	**Apply Curves**	applies the guides to the contour. It will be temporally and spatially changed. The guide overwrites the initial model defined in the previous workflow step and looks for a certain amount of frames to establish a new contour in this area.  The contour guide is meant to change wrong temporal interpretation of the endocardial contour (e.g. Papillary muscle, Mitral valve opening). If the contour over the entire heart cycle has to be replaced it is recommended either to change the Contour Detection Sensitivity or to redraw the initial contour within the **Initial Contour** Workflow step.
Beutel Display Settings (Beutel can be statically as well as dynamically displayed.)		

	**Beutel Transparency**	determines the appearance of the Beutel. A value of 0 creates a solid surface. Increasing this value the transparency of the Beutel is increased too. A high transparency setting might be helpful to display higher velocities in the center of a velocity profile.
	**Display Beutel**	displays the Beutel surface.
	Display **Wireframe**	displays a mesh Beutel.

3.10 4D LV Analysis

The **4D LV Analysis** Display can be entered via the **4D LV Analysis**  button.

Beutel SAX view from Apex to base within MPR	**Beutel LAX view within MPR**
Polarplot	**Result view displayed as chart**

Tiles at the step: 4D LV Analysis

Mouse functions at Workspace

Button	Function
Left Mouse Button in the MPR views	Keep the left mouse button pressed on to the double arrow on top of the SAX level LOI or the LAX orientation LOI and move the mouse to: • rotate the LOI around the LAX in the Beutel SAX view. The Beutel of the Beutel LAX view will be rotated around its LAX and the MPR will be modified accordingly. • shift the LOI up/down the LAX in the Beutel LAX view. The MPR of the Beutel SAX view will be modified accordingly.
Left Mouse	highlights a curve at the Result view corresponding with the

pointer within the Bull's eye	segment, where the mouse pointer is positioned. With a click into the segments of the bull's eye the corresponding segment will be disabled from calculation of the SDI. Use the disabling of segments when contours of the segment do not match the endocardium (e.g. LVOT).
Left Mouse pointer in charts view	highlights a curve at the Result view corresponding with the segment, where the mouse pointer is positioned. Keep the left mouse button pressed on the circle  to reposition the regional minima if necessary.
Mouse Wheel if available	**Mouse pointer within Workspace:** Rotate the mouse wheel to rotate the LOI around the LAX in the Beutel SAX view. The Beutel of the Beutel LAX view will be rotated around its LAX and the MPR will be modified accordingly.
Right Mouse Button	Perform a right mouse click on a polar plot segment to align the SAX and LAX views. The SAX and LAX view MPRs corresponding to the segment are displayed.

Toolbar

Button	Name	Function
	**Locked Navigation**	locks/unlocks the function of the button Pivot/Orbit.  Locking an unlocked navigation resets the views.
	**Pivot / Orbit**	Keep the left mouse button pressed and move the mouse to rotate the selected Beutel around its vertical/horizontal axis. This action can also be performed by using the middle mouse button without activating the Pivot/Orbit button before.

Button, slider, icon	Name	Function
	**Brightness**	lightens or darkens tissue and colors equally.
	**Contrast**	adjusts the difference between light and dark tissue as well as light and dark colors.

Segment Models

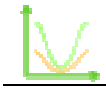
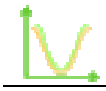
Segment models allow the regional analysis of the LV chamber. It provides the functionality to divide the surface of a Beutel into segment models and thus to assign each surface point to a segment. Following segment models are available:

	**Global**	displays the Global Volume of LV.
	**16 Segment Model**	applies the 16 Segment model to Beutel and polarplot(2 dimensional illustration of the surface of the left ventricle. The surface can be covered by different maps (e.g. Bull's eye)). Further volume (or normalized volume) curves are displayed with their assigned colors correspondent to the segment colors of Beutel and polarplot.

Results

Within the Result view, two different display modes are available:

- Measurement values
- Graphs

	**Text Display**	displays a list of calculated measurements.
	**Chart, Absolute**	displays the graphs of Volume[ml]/Time[ms, %]. (absolute)
	**Chart, Normalized**	displays the graphs of Volume[%]/Time[ms, %]. (normalized to their individual maximum)

Beutel Display Settings (Beutel and MPR can be statically as well as dynamically displayed.)

	**Beutel Transparency**	determines the appearance of the Beutel. A value of 0 creates a solid surface. Increasing this value the transparency of the Beutel is increased too. A high transparency setting might be helpful to display higher velocities in the center of a velocity profile.
	**Display Beutel**	displays the Beutel surface.
	**Display Wireframe**	displays a mesh Beutel.

Temporal Units (The display of the temporal unit can be toggled between **ms** or %.)

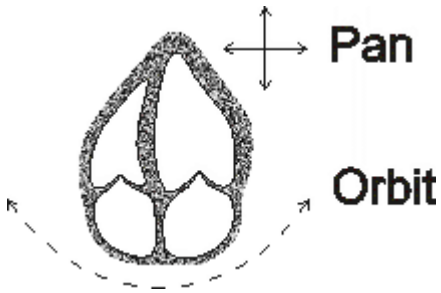
4 Quick Guide

Starting 4D LV-Function

4D LV-Function is started from Host System. 4D LV-Function immediately starts with the Selected Image or the user has to select the Selected Image or an available Bookmark before. Position the mouse pointer on an item, open the context menu with a right mouse click the context menu and select 4D LV-Function.

View Adjustment

1.) Enter the View Adjustment Display via the button.
2.) **Adjust long axis.** Use the Brightness and Contrast sliders to display the dataset with the specific details needed for your analysis. The A4Ch view is used as reference plane for spatial relation between segment model and physical heart.
Use the Mouse functions Pivot(Left click and hold) and Pan(Right click and hold) mode for MPR manipulations to align the data with the LAX view. Determine the A4Ch view. Now the data set is registered with the 16 segment model. After that check whether the result of the other two views (By clicking on the respective buttons 2Ch and LAX to view) satisfy your demands. If not, adapt the view(s) to your satisfaction.



Adjust long axis

Initial Contours

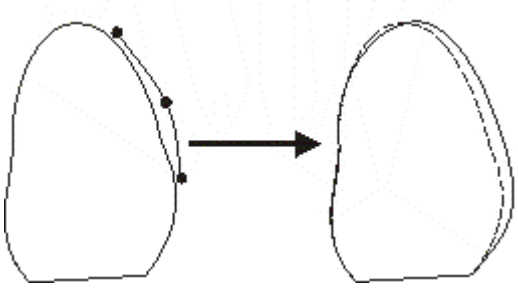
1.) Enter the Beutel Initialization Display via the button.
2.) **Set initial contours.** Use the default View to trace the contours at the endsystolic and enddiastolic static images or select another one. Place the first point of the contour spline with a click within one of the static images at the upper or lower right tiles. Trace the contour (green) and define the position of the last spline point with a double click. Redo this at the other static image.
3.) **Select another view.** Check the position of the shown extrapolated initial contours in turquoise based on the preceded initial contours. If this extrapolated contour does not meet the expectations of the user, your own contour tracing can be performed. It replaces the default one. Check the displayed contour proposal at all views.

Tiles at the step: Beutel Initialization

Contour Revision

1.) Enter the Beutel Revision Display via the  button.
2.) Check the represented contours against the anatomical structures given in the MPRs. If they do not match the anatomical structures, the user has two possibilities to adapt the Beutel(contours).
3.) **Use the Contour detection sensitivity** to adapt the contour finding to the attributes and the quality of the dataset. The contour finding algorithm can calculate with three different settings. Choose the button, which produces the best contour.

4.) **Use the Add Curve**  button to draw guides into the MPR views to specify desired positions of the Beutel surface. Define single points with left mouse clicks and finish the tracing with a double click. Apply these changes with clicking the **Apply Curves**  button.



Add Curve

4D LV Analysis

1.) Enter the 4D LV Analysis Display via the  button. It represents the calculated results (Beutels, polarplot and numerous Curves) of the steps performed before.
2.) **Select a Segment Model** to see the Beutel surface and the polarplot with the current segment model with solidly filled segments. Regional volume is used as underlying measurement values for the given segment model.

3.) **Select the kind of result representation** choosing from measurement values or graphs.

Storing reworked study

Close and save the current study via the **Exit**  button. Type in a name for your analysis and confirm with Yes to store the reworked study together with its results. 4D LV-Function will be exited.

5 Technical Information

Product I.D: T.08.0099

Product Name: 4D LV-Function© 2.2

Effective Date: 18-Jun-07

5.1 General Information

5.1.1 Safety Classification

According to MDD, 4D LV-Function is classified as a Class IIa product.

5.2 Technical Specification

5.2.1 Software Features

TomTec Automated Contour Detection (TACD©)

- Automated calculation of ED(End Diastolic) and ES(End Systolic) phase for drawing initial contours
- Drawing initial contours in 4CH- and/or 3CH- and/or 2CH-view
- Automated detection of endocardial border in 3D space
- Interaction with TACD© by
  - Changing contour detection sensitivity
  - Partial contour correction by adding guides

4D Review and Analysis

- Real-time interactive 4D model (beutel) display of ventricle
- Display of original 2D ultrasound slices (SAX and LAX) with beutel as overlay
- Different graph displays for global as well as regional volume over time curves
- Display of result window with derived parameters
- 16-Segment display on 4D model surface
- Switch from global to regional analysis
- Activation/deactivation of single segments

Measurements

- Calculation of EDV, ESV, EF and SV
- Regional and global volumes over time
- Calculation of SDI (Systolic Dyssynchrony Index)

Storeback and Export

- Bookmark store back
- Measurement store back
- Export of screenshots

5.3 Hardware Requirements

5.3.1 Basic Requirements

The 4D LV-Function Software requires a high performance platform as base unit.

	Minimum	Recommended
Operating System	Microsoft® Windows™ XP (SP2) or Microsoft® Windows™ XP Embedded	Microsoft® Windows™ XP (SP2) or Microsoft® Windows™ XP Embedded
CPU	Intel® Pentium® IV 2.4 GHz	Intel® Pentium® IV 2.4 GHz
RAM	1 GB	1 GB
Graphic Card	ATI Radeon X800 Pro	ATI Radeon X800 Pro

6 Regulatory Information

The 4D LV-Function application is tested to meet applicable requirements in relevant EU directives and European /International standards. (See “Standards used” below). Any changes to this application must be approved by TomTec Imaging Systems GmbH, manufacturer of this application.
Ignoring this advice may compromise the regulatory approvals obtained for the product.

Please contact the TomTec representative for further advice.

Standards used

The TomTec Imaging Systems GmbH 4D LV-Function software is a Class IIa device, according to the Medical Devices Directive 93/42 EEC.
To fulfill the requirements of relevant EC directives and European Harmonized/International standards, the following documents/standards have been used:

Standard / Directive
EN ISO 9001:2000
EN ISO 13485:2003
EN ISO 14971:2007
EN 980:2003

CE 0123

7 End-User Licence Agreement

IMPORTANT – READ CAREFULLY: This TomTec End-User License Agreement (**"TEULA"**) is a legal agreement between you (either an individual or a single entity) and TomTec Imaging Systems GmbH for the TomTec software product identified above, which includes computer software and may include associated media, printed materials, and "online" or electronic documentation (**"SOFTWARE PRODUCT"**). By installing, copying, or otherwise using the **SOFTWARE PRODUCT**, you agree to be bound by the terms of this **TEULA**. If you do not agree to the terms of this **TEULA**, do not install or use the **SOFTWARE PRODUCT**; you may, however, return it to your place of purchase for a full refund.

7.1 Software Product License

The **SOFTWARE PRODUCT** is protected by copyright laws and international copyright treaties, as well as other intellectual property laws and treaties. The **SOFTWARE PRODUCT** is licensed, not sold.

1.) GRANT OF LICENCE.

This **TEULA** grants you the following rights:

- **Applications Software.** You may install and use one copy of the **SOFTWARE PRODUCT**, or any prior version for the same operating system, on a single computer. The primary user of the computer on which the **SOFTWARE PRODUCT** is installed is not allowed to make a second copy for his or her exclusive use on a portable computer.
- **Storage / Network Use.** You may also store or install a copy of the **SOFTWARE PRODUCT** on a storage device, such as a network server, used only to install or run the **SOFTWARE PRODUCT** on your other computers over an internal network; however, you must acquire and dedicate a license for each separate computer on which the **SOFTWARE PRODUCT** is installed or run from the storage device. A license for the **SOFTWARE PRODUCT** may not be shared or used concurrently on different computers.
- **License Pak.** If you have acquired this **TEULA** in a TomTec License Pak, you may make the number of additional copies of the computer software portion of the **SOFTWARE PRODUCT** authorized on the printed copy of this **TEULA**, and you may use each copy in the manner specified above. You are also not entitled to make a corresponding number of secondary copies for portable computer use.

2.) DESCRIPTION OF OTHER RIGHTS AND LIMITATIONS.

- **Not for Resale Software.** If the **SOFTWARE PRODUCT** is labeled "Not for Resale" or "NFR," then, notwithstanding other sections of this **TEULA**, you may not resell, or otherwise transfer for value, the **SOFTWARE PRODUCT**.
- **Limitations on Reverse Engineering, Decompilation, and Disassembly.** You may not reverse engineer, decompile, or disassemble the **SOFTWARE PRODUCT**, except and only to the extent that such activity is expressly permitted by applicable law notwithstanding this limitation.

- **Separation of Components.** The **SOFTWARE PRODUCT** is licensed as a single product. Its component parts may not be separated for use on more than one computer.
- **Rental.** You may not rent, lease, or lend the **SOFTWARE PRODUCT**.
- **Support Services.** TomTec may provide you with support services related to the **SOFTWARE PRODUCT** ("Support Services"). Use of Support Services is governed by the TomTec policies and programs described in the user manual, in "online" documentation, and/or in other TomTec-provided materials. Any supplemental software code provided to you as part of the Support Services shall be considered part of the **SOFTWARE PRODUCT** and subject to the terms and conditions of this **TEULA**. With respect to technical information you provide to TomTec as part of the Support Services, TomTec may use such information for its business purposes, including for product support and development. TomTec will not utilize such technical information in a form that personally identifies you.
- **Software Transfer.** You may permanently transfer all of your rights under this **TEULA**, provided you retain no copies, you transfer all of the **SOFTWARE PRODUCT** (including all component parts, the media and printed materials, any upgrades, this **TEULA**, and, if applicable, the Certificate of Authenticity), and the recipient agrees to the terms of this **TEULA**. If the **SOFTWARE PRODUCT** is an upgrade, any transfer must include all prior versions of the **SOFTWARE PRODUCT**.
- **Termination.** Without prejudice to any other rights, TomTec may terminate this **TEULA** if you fail to comply with the terms and conditions of this **TEULA**. In such event, you must destroy all copies of the **SOFTWARE PRODUCT** and all of its component parts.

3.) Languages.

By installing, copying, or otherwise using the **SOFTWARE PRODUCT**, you agree to accept the languages which the **SOFTWARE PRODUCT** offers.

4.) UPGRADES.

If the **SOFTWARE PRODUCT** is labeled as an upgrade, you must be properly licensed to use a product identified by TomTec as being eligible for the upgrade in order to use the **SOFTWARE PRODUCT**. A **SOFTWARE PRODUCT** labeled as an upgrade replaces and/or supplements the product that formed the basis for your eligibility for the upgrade. You may use the resulting upgraded product only in accordance with the terms of this **TEULA**. If the **SOFTWARE PRODUCT** is an upgrade of a component of a package of software programs that you licensed as a single product, the **SOFTWARE PRODUCT** may be used and transferred only as part of that single product package and may not be separated for use on more than one computer.

5.) COPYRIGHT.

All title and copyrights in and to the **SOFTWARE PRODUCT** (including but not limited to any images, photographs, animations, video, audio, music, text, and "applets" incorporated into the **SOFTWARE PRODUCT**), the accompanying printed materials, and any copies of the **SOFTWARE PRODUCT** are owned by TomTec or its suppliers. The **SOFTWARE PRODUCT** is protected by copyright laws and international treaty provisions. Therefore, you must treat the **SOFTWARE PRODUCT** like any other copyrighted material except that you may install the **SOFTWARE PRODUCT** on a single computer provided you keep the original solely for backup or archival purposes. You may not copy the printed materials accompanying the **SOFTWARE PRODUCT**.

6.) DUAL-MEDIA SOFTWARE.

You may receive the **SOFTWARE PRODUCT** in more than one medium. Regardless of the type or size of medium you receive, you may use only one medium that is appropriate for your single computer. You may not use or install the other medium on another computer. You may not loan, rent, lease, or otherwise transfer the other medium to another user, except as part of the permanent transfer (as provided above) of the **SOFTWARE PRODUCT**.

7.) Miscellaneous.

If any provision of this **TEULA** shall be declared by any court of competent jurisdiction to be illegal, void or unenforceable, all other provisions of this **TEULA** shall not be affected and shall remain in full force and effect.
D.31.0001/03

8 Index